

REMARKS

The amendments above and these remarks are responsive to the non-final Office action dated May 1, 2007, and are being filed under 37 C.F.R. § 1.111. Claims 5–9, 11, 13–15, 17–26, 28, and 31–40 are pending in the application. In the Office action, the Examiner rejected each of the pending claims as follows:

- Claims 5–9, 11, 13–15, 17–19, 21–25, 35–38, and 40 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0001119 A1 to Lombardo (“Lombardo”);
- Claims 28 and 31–33 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,456,005 to Lichty (“Lichty”);
- Claim 26 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lombardo;
- Claims 34 and 39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lombardo in view of U.S. Patent No. 5,743,912 to Lahille et al. (“Lahille”); and
- Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lombardo in view of U.S. Patent No. 6,048,344 to Schenk (“Schenk”).

Applicants traverse the rejections, contending that all of the claims are patentable over the cited references. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants want to patent now, applicants have amended claims 5–9, 11, 13–15, 17–26, 28, and 33–40. However, applicants reserve the right to pursue the subject matter of original or previously presented versions of the amended claims at a later time. Furthermore, applicants have presented arguments showing that all of the pending claims are patentable over the cited references. Accordingly, applicants respectfully request reconsideration of the application in view of the amendments above and the remarks

below, and prompt issuance of a Notice of Allowability covering all of the pending claims.

I. Amendments to the Claims

The present communication amends pending claims 5–9, 11, 13–15, 17–26, 28, and 33–40. The amendments to the claims are supported fully by the application. Exemplary support (and/or an explanation) for each claim amendment is included, without limitation, in the following table:

<i>Claim</i>	<i>Exemplary Support (and/or Explanation)</i>
5 (Independent)	Claim 28; Page 5, lines 9-13; Figure 2 (Amended to recite a method)
6–9, 11, 13–15, 17–20, and 34	(Address formal issues created by the amendments to claim 5)
21 (Independent)	Claim 28; Page 5, lines 9-13; Figure 2 (Amended to recite a method)
22–26	(Address formal issues created by the amendments to claim 21)
28 (Independent)	Page 5, lines 9-13; Figure 2
33	(Improves clarity)
35 (Independent)	Claim 28; Page 5, lines 9-13; Figure 2 (Amended to recite a method)
36–40	(Address formal issues created by the amendments to claim 35)

II. Claim Rejections – 35 U.S.C. §§ 102 and 103

The Examiner rejected each of the pending claims as being anticipated or obvious. Applicants traverse the rejections, contending that the cited references, taken alone or in combination, do not teach or suggest every element of any of the rejected claims. Nevertheless, for the reasons set forth above, applicants have amended each of the pending independent claims, namely, claims 5, 21, 28, and 35. Each of the independent claims, and all of the claims depending therefrom, are patentable for at least the reasons set forth below.

A. Claims 5–9, 11, 13–15, 17–20, and 34

Independent claim 5, as amended, is now directed to a method and reads as follows in clean form:

5. (Currently Amended) A method of compressing a bone, comprising:
- selecting a bone screw including
 - a shank including a thread disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone, and
 - a head connected to the shank and defining a plurality of ledge structures disposed at spaced positions generally along the head, each ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and
 - installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the ledge structures and is urged toward a portion of the bone near the shank.

In the Office action, claim 5 was rejected as being anticipated by Lombardo. However, Lombardo does not teach or suggest every element of amended claim 5. For example,

Lombardo does not teach or suggest (1) selecting a bone screw including a head defining a plurality of ledge structures with each ledge structure “extending partially or completely around the head to define a respective plane” or (2) “installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the ledge structures.”

Lombardo relates to a surgical screw system for use with implantation rods. Figures 2 and 4 of Lombardo, which are reproduced here to facilitate review, present an exploded view of components of the surgical screw system (Figure 2) or a perspective view of the system assembled with an implantation rod (Figure 4).

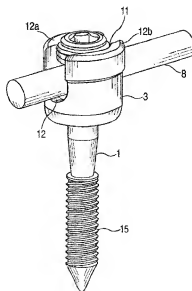
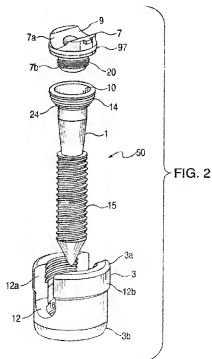


FIG. 4

The surgical screw system includes a screw member 1 with a head 14 and a shaft 15. The surgical screw system also includes a receiver member 3 defining an axial bore 16 for receiving the screw member and a U-shaped channel 12 for receiving an implantation rod 8. The surgical screw system further includes a pressure cap 7 and a

locking device 11 for engaging and securing screw member 1 and rod 8 relative to receiver member 3.

Figure 1, which is reproduced here to facilitate review, presents a sectional view of the surgical screw system assembled with rod 8. Head 14 of screw member 1 is disclosed to include a spherical undersurface 24 forming a threaded portion 33 (paragraphs [0007] and [0031]). Shaft 15 also has a threaded portion 33, apparently to allow the screw member to be screwed into the spinal column of a patient (claim 18).

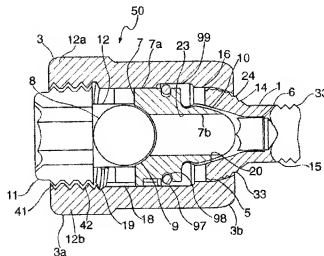


FIG. 1

In the Office action, the Examiner asserted that the head of Lombardo's screw member defines a plurality of ledge structures, as recited by claim 5. Applicants disagree because Lombardo discloses a threaded portion on the head, which one of skill in the art would have interpreted as including a helical rib, not the recited ledge structures. In particular, claim 5 recites that each ledge structure extends "partially or completely around the head to define a respective plane disposed orthogonally to the long axis."

Nevertheless, even if Lombardo is interpreted as disclosing a plurality of ledge structures, and applicants contend that the reference does not, Lombardo does not teach or suggest "installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the ledge structures," as recited by claim 5. Lombardo does not explicitly disclose the position of head 14 of screw member 1 relative to bone after installation. However, as illustrated by Figure 1 of Lombardo (see above), Lombardo discloses placement of at least most of head 14 of screw member 1 inside receiver member 3, such that at least most of head 14 is not accessible for bone engagement. Furthermore, shaft 15 of screw member 1 has a structure that restricts full advancement of the shaft into bone. In particular, as illustrated below in applicant's annotated version of Figure 4 of Lombardo, the threaded portion of shaft 15 terminates in an annular flange.

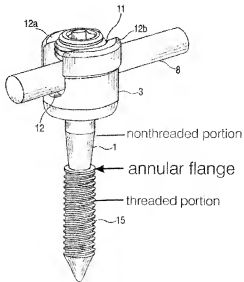


FIG. 4

Applicants submit that the annular flange is designed to, or at least would function to, stop threaded advancement of shaft 15 into bone when the annular flange contacts

bone, since the annular flange cannot follow the helical thread path in bone that is followed by the threaded portion of the shaft. As a result, when fully installed, head 14, receiver member 3, and rod 8 would be spaced from bone via a nonthreaded portion of the shaft, which would allow the tilt of receiver member 3 to be adjusted relative to screw member 1 without interfering contact with bone, consistent with Lombardo's stated "two-dimensional adjustment and multi-axial capabilities" for the system (paragraph [0037]). Accordingly, applicants submit that Lombardo does not disclose the step of installing recited by claim 5 and further that Lombardo's device, or even screw member 1 alone, would be unsuitable for use in the method of claim 5.

In summary, Lombardo does not teach or suggest every element of amended claim 5. Accordingly, claim 5 should be allowed. In addition, claims 6–9, 11, 13–15, 17–20 and 34, which depend from claim 5, also should be allowed for at least the same reasons as claim 5.

B. Claims 21–26

Independent claim 21, as amended, is now directed to a method and reads as follows in clean form:

21. (Currently Amended) A method of compressing a bone, comprising:
- selecting a bone screw including
 - a shank including a proximal region, a distal region, and a thread disposed externally for threaded engagement with bone and restricted to the distal region, and
 - a head connected to the shank and spaced from the thread by the proximal region, the head defining a plurality of spaced ledge structures disposed generally along the head, each ledge structure extending in a respective plane to describe at least an arc of a circle; and

installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the ledge structures and is urged toward a portion of the bone near the shank.

In the Office action, claim 21 was rejected as being anticipated by Lombardo. However, Lombardo does not teach or suggest every element of claim 21. For example, and for at least the same general reasons as those presented above in relation to claim 5, Lombardo does not teach or suggest (1) selecting a bone screw including a head defining a plurality of spaced ledge structures with “each ledge structure extending in a respective plane to describe at least an arc of a circle” or (2) “installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the ledge structures.” Claim 21 thus should be allowed. In addition, claims 22–26, which depend from claim 21, also should be allowed for at least the same reasons as claim 21.

C. Claims 28 and 31–33

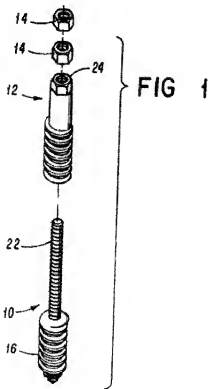
Independent claim 28 is directed to a method and, as amended, reads as follows in clean form:

28. (Currently Amended) A method of compressing a bone with a bone screw, comprising:
forming a hole in the bone;
selecting a bone screw having a shank and a head connected to the shank, the head defining a plurality of ledge structures disposed at spaced positions generally along the head, each ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and

advancing first the shank and then the head of the bone screw into the hole via threaded engagement of the shank with the bone such that a portion of the bone near the head is engaged by one or more of the ledge structures and is urged toward a portion of the bone near the shank.

In the Office action, claim 28 was rejected as being anticipated by Lichty. However, Lichty does not teach or suggest every element of claim 28. For example, Lichty does not teach or suggest advancing the bone screw "such that a portion of the bone near the head is engaged by one or more of the ledge structures."

Lichty relates to a bone fixation device for bone compression. The device is illustrated in an exploded view in Figure 1 of Lichty, which is reproduced here to facilitate review. The device consists of a distal part 10, a proximal part 12, and two nuts 14.



Figures 2-4 of Lichty, which are reproduced here to facilitate review, illustrate the fixation device being installed in a fractured bone.

FIG 2

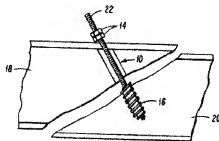


FIG 3

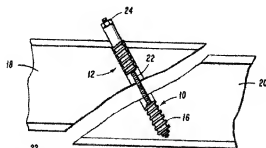
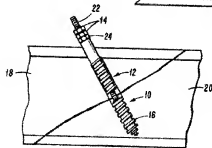


FIG 4



In Figure 2, a bore has been formed partly through the fractured bone such that the bore extends through proximal fragment 18 and into distal fragment 20. Distal part 10 has been driven into bone by placing nuts 14 onto threaded upper shaft 22 and then by using a tool to drive externally threaded body 16 of distal part 10 into threaded engagement with distal fragment 20 by engagement and rotation of nuts 14 with the tool.

In Figure 3, proximal part 12 of the device is placed over upper shaft 22. Proximal part 12 then is driven rotationally into proximal fragment 18 via a hex head 24

that is integral with or affixed to an externally threaded body of proximal part 12. Significantly, proximal part 12 is not advanced fully into proximal part 12, and thus hex head 24 protrudes from the bone.

In Figure 4, proximal and distal fragments 18, 20 are compressed by placing nut 14 onto and in threaded engagement with upper shaft 22 and then turning the nut such that the nut bears against hex head 24 and urges proximal part 12 toward distal part 10, thus urging proximal fragment 18 toward distal fragment 20. An additional nut 14 then may be threaded onto upper shaft 22. Significantly, Lichty states that “both of nuts 14 as well as hex head 24 extend outside of the skin surface” (col. 3, lines 17 and 18). In other words, neither of nuts 14 engages bone at any time during installation of the device.

In the Office action, the Examiner asserted that nuts 14 provide the recited ledge structures of the head. However, claim 28 recites advancing “the head of the bone screw into the hole” in the bone. Lichty does not disclose advancement of either nut 14 into bone (e.g., see Figures 2 and 4 of Lichty). In any event, applicants have amended claim 28 to recite advancing the head of the bone screw into the hole “such that a portion of the bone near the head is engaged by one or more of the ledge structures.” As noted above, nuts 14 of Lichty never engage bone. Accordingly, claim 28 is patentable over Lichty and should be allowed. In addition, claims 31–33, which depend from claim 28, also should be allowed for at least the same reasons as claim 28.

D. Claims 35–40

Independent claim 35, as amended, is now directed to a method and reads as follows in clean form:

35. (Currently Amended) A method of compressing a bone, comprising:

 selecting a bone screw including

 a shank including a thread disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone, and

 a head connected to the shank and including a plurality of spaced shoulders of different diameter, each shoulder facing generally in the direction of advancement and extending partially or completely around the long axis in a respective path defining a plane; and

 installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the shoulders and is urged toward a portion of the bone near the shank.

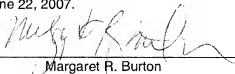
In the Office action, claim 35 was rejected as being anticipated by Lombardo. However, Lombardo does not teach or suggest every element of claim 35. For example, and for at least the same general reasons as those presented above in relation to claim 5, Lombardo does not teach or suggest (1) selecting a bone screw including a head that includes “a plurality of spaced shoulders of different diameter,” with each shoulder “extending partially or completely around the long axis in a respective path defining a plane,” or (2) “installing the bone screw in a bone such that a portion of the bone near the head is engaged by one or more of the shoulders.” Claim 35 thus should be allowed. In addition, claims 36–40, which depend from claim 35, also should be allowed for at least the same reasons as claim 35.

IV. Conclusion

Applicants submit that each of the pending claims is patentable over the cited references. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record, or his associate Stan Hollenberg (Reg. No. 47,658), both at (503) 224-6655.

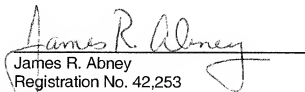
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Respectfully submitted,

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